

REMARKS

This is a Request for Continued Examination (RCE) in response to the Final Office Action mailed March 9, 2006, in which a two (2) month Shortened Statutory Period for Response expired on May 9, 2006 and the three (3) month due date for responding expired on June 9, 2006. Claims 1, 6, 11, 19, 21, 30 and 37 have been amended. Claims 39-51 have been added. Claim 29 has been canceled. No new matter has been added to the application. Claims 1-16, 18-28, and 30-51 are now pending.

REJECTIONS UNDER 35 U.S.C. § 103 (CLAIMS 1-16, AND 18-20)

The Examiner has rejected claims 1-4, 9-16, 18-24, and 28-38 under 35 U.S.C. §103(a) as allegedly being unpatentable by U.S. Patent Publication No. 2003/0018309 to Breznock in view of U.S. Patent No. 4,813,941 to Shea. The Examiner contends that it would have been obvious to one of ordinary skill in the art to add the adhesive strips of Shea to the tubular device of Breznock for the purpose of securing the tubular device to the skin of the patient. Of the rejected claims, claims 1 and 21 are independent claims. Applicant respectfully traverses the rejections.

Breznock teaches a tubular device, such as a cannula, tube, or catheter to be placed in the thoracic cavity of a patient (Abstract). The tubular device serves as a conduit for drainage of excessive fluid or air buildup in the chest and also restricts influx of fluid or air into the chest cavity, which may prevent pneumothorax or infection (Abstract). The tubular device includes an intracorporeal fixation mechanism that cooperates with an extracorporeal fixation mechanism to prevent outward and inward movement, respectively, of the tubular device (page 1, ¶ 0010). Breznock teaches that one embodiment of the intracorporeal fixation mechanism is a balloon inside the patient's chest, the balloon is larger than the chest incision, and the balloon is inflated after the tubular device is placed in the patient's chest (page 4, ¶ 0040).


25315

CUSTOMER NUMBER

- 9 -

GMMD-1-1002RCE

BLACK LOWE & GRAHAM^{PLLC}


701 Fifth Avenue, Suite 4800
Seattle, Washington 98104
206.381.3300 • F: 206.381.3301

Breznock also teaches that the extracorporeal fixation mechanism operates to prevent the tubular device from being inadvertently pushed further into the patient's chest than intended (page 4, ¶ 0042). The extracorporeal fixation mechanism accomplishes this objective by releasably engaging (*e.g.*, clamping, crimping, squeezing, etc.) the tubular device exterior to the patient's skin (page 4, ¶ 0042). Breznock provides that one embodiment of the extracorporeal fixation mechanism is a lockable clip device that slides over the tubular device and is then locked onto the tubular device at a desired location (page 4, ¶ 0043). Alternatively, Breznock teaches that the extracorporeal fixation mechanism may be an inflatable balloon or an opposably engaged spring clip that encircles the tubular device (page 4, ¶¶ 0044-0045). Fixation of the extracorporeal fixation mechanism may be enhanced with polymeric tabs that penetrate the patient's skin, yet permit the extracorporeal fixation mechanism to be sutured to the skin (page 4, ¶ 0046). In one embodiment, Breznock teaches that a distal side of the extracorporeal fixation mechanism includes an adhesive layer to facilitate not only fixation to the skin, but provide a contamination barrier at the entry site (*e.g.*, incision site).

Shea also describes an apparatus for providing temporary treatment of pneumothorax in a patient (Abstract). Shea teaches that the apparatus includes an exhaustion device with a standard luer lock lug receptacle coupled to a one-way valve (Abstract). The apparatus may include projecting wings for gripping the apparatus and providing attachment surfaces to secure the apparatus to the patient (Abstract; column 3, lines 51-54; and Figures 6 and 7). Alternatively, Shea teaches that tape or other adhesive strips can be attached directly to the housing of the luer lock lug receptacle housing, where a first end is attached to the housing while a free end is pressed onto the patient's skin (column 4, lines 3-12; and Figure 8).

As amended herein, claim 1 recites, *inter alia*, “an at least one flexible band having a first end and a second end, the first end coupled to the hub; *and an at least one adhesively coated tab attached to the at least one flexible band*, the at least one adhesively coated tab attachable to a portion of skin near the body cavity to mechanically affix the catheter assembly to the skin” (emphasis added). Breznock and Shea, either individually or in combination, do not teach, suggest, or provide any motivation for at least one adhesively coated tab attached to at least one flexible band. In contrast, Breznock merely provides a passing



suggestion that the extracorporeal fixation mechanism (*e.g.*, clip or balloon) may include an adhesive layer to facilitate fixation of the tubular device to the skin. Breznock does not teach or suggest that the extracorporeal fixation mechanism with the adhesive layer comprises a tab attached to a band, which is further coupled to a hub.

Likewise, Shea merely teaches using adhesive strips that are either taped to projecting wings or taped to a one-piece outer housing. Shea does not teach or suggest that any of the adhesive strips comprise a tab attached to a band, which is further coupled to the wings or housing. Furthermore, the teachings of Breznock and Shea, either individually or in combination, do not teach, suggest, or provide any motivation that the adhesive means taught therein would be sufficient to affix the pneumothorax device to the patient in a manner that maintains the pneumothorax device in an operative posture after installation and without further assistance or support from medical personnel.

Accordingly, claim 1 is patentable over Breznock in view of Shea. Claims 2-16, 18-20, and 39-43, which depend from claim 1, are allowable because they depend from an allowable base claim. *In re Fine*, 837 F.2d 1071, 5 USPQ.2d 1596 (Fed. Cir. 1988) (“[d]ependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious.”)

REJECTIONS UNDER 35 U.S.C. § 103 (CLAIMS 21-38)

For the reasons expressed above regarding the patentability of claim 1, independent claim 21, along with claims 22-28 and 30-38 which depend from claim 21, are also patentable over Breznock in view of Shea. Claim 29 has been canceled herein.

REJECTIONS UNDER 35 U.S.C. § 103 (CLAIM 5)

The Examiner rejected claim 5, which depends from independent claim 1, under Section 103(a) as being unpatentable over Breznock in view of Shea and further in view of U.S. Patent No. 5,693,031 to Ryan et al. (Ryan). Ryan does not teach, suggest, or provide any motivation for the aforementioned aspect of claim 1, specifically “at least one adhesively coated tab attached to the at least one flexible band.” In view of this and because claim 5 contains all the limitations of

independent claim 1, plus at least one additional limitation, claim 5 is patentable over Breznock, Shea, and Ryan, either individually or in some combination.

REJECTIONS UNDER 35 U.S.C. § 103 (CLAIMS 6-8 AND 25-27)

Lastly, the Examiner rejected claims 6-8 and 25-27, which depend from claims 1 and 21, respectively, under Section 103(a) as being unpatentable over Breznock in view of Shea and further in view of U.S. Patent No. 3,703,899 to Calinog. Because Calinog does not teach, suggest, or provide any motivation for the inventive limitations in independent claims 1 and 21, and for the reasons expressed above with regard to claim 5, dependent claims 6-8 and 25-27 are patentable over Breznock, Shea, and Calinog, either individually or in some combination.

NEWLY ADDED CLAIMS (CLAIMS 39-51)

Claims 39-51 have been added. Claims 39-46 depend from claim 1. Claims 47-51 depend from claim 21. Although the language of these claims may differ from some of the other claims, Applicant submits that these dependent claims are patentable over the cited references for at least the reason that they depend from respective allowable independent claims. In addition, these dependent claims may be patentable for other reasons that have not been discussed herein.

CONCLUSION

Overall, the cited references do not singly, or in any motivated combination, teach or suggest the claimed features of the embodiments recited in independent claims 1 and 21, and thus such claims are allowable. The remaining claims depend from the allowable independent claims, and they include additional limitations, therefore such claims are likewise allowable. If the undersigned attorney has overlooked a relevant teaching in any of the references, the Examiner is requested to point out specifically where such teaching may be found.

For the reasons discussed above, the references relied upon by the Examiner are insufficient to establish a *prima facie* case of obviousness. Applicant respectfully requests that the Examiner reconsider this application, withdraw the §103(a) rejections, and timely allow all pending claims. Examiner McCorkle is encouraged to contact Mr. Vershave by telephone to promptly address any issues or concerns.

Respectfully submitted,

BLACK LOWE & GRAHAM^{PLLC}



Richard C. Vershave

Registration No. 55,907